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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,207	11/24/2003	Chang Yi Wang	1151-4153US2	8598

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	**PAPER NUMBER**
1644	

NOTIFICATION DATE	DELIVERY MODE
12/15/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/723,207	WANG ET AL.	
	Examiner	Art Unit	
	NORA M. ROONEY	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,7 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3, 7 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response filed on 08/22/2008 is acknowledged.

2. Claims 3, 7 and 10 are currently pending and under consideration as they read on a peptide immunogen comprising SEQ ID NO:5-8 or 84 and a promiscuous T cell epitope.

3. In view of Applicant's response filed on 08/22/2008, only the following rejections are maintained.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

> A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
> Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 3, 7 and 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-6 of U.S. Patent No. 6,713,301 (PTO-892; Reference A). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to synthetic peptide-which comprises (a) a promiscuous helper T cell epitope (artificial helper T ell epitope in the '301 Patent) , (b) an IgE-CH3 domain antigen peptide, wherein said IgE-CH3 domain antigen peptide i) is 25 acids in length ii) contains two cysteine residues separated by about 23 amino acid residues, and iii) is selected from the group consisting of SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:84 wherein from one to four of the residues in SEQ ID NO:5 is conservatively substituted (Target antigenic site in the '301 Patent); and optionally (c) an immunostimulatory invasin domain, SEQ ID NO: 13 (General immunostimulatory sequence of SEQ ID NO:78 in the '301 patent) in instant claim 3, wherein the synthetic peptide induces anti-IgE antibody production in a mammal in instant claim 7; and wherein said helper T cell epitope is an SSAL epitope and wherein said helper T cell epitope has an amino acid sequence selected from the group consisting of SEQ ID NOS: 9-12, SEQ ID NOS: 61-82, and SEQ ID NO: 89 (artificial helper T ell epitope in the '301 Patent) in instant claim 10 for the same reasons as set forth in the Office Action mailed on 07/01/2008.

Applicant's arguments filed on 08/22/2008 have been fully considered, but are not found persuasive.

Applicant argues:

"Thus, claims 2-6 are directed to a method of using the Th epitopes to prepare a peptide immunogen. The "target antigenic site" is defined as a B-cell epitope, a peptide hapten, and a immunologically reactive analog thereof. There is no recital of an IgE-CH3 epitope. There is no recital of a peptide immunogen for the treatment of allergy.

In contrast, the claims of the present application is specifically directed to peptide immunogens for the treatment of allergy, where a B-cell epitope of the present claimed invention is derived from IgE-CH3 and is specific. There is no disclosure, description or suggestion of the IgE-CH3 B-cell epitopes of the present application in the '301 patent. The B-cell epitope is a fragment oflgE-CH3. It is not anticipated by or obvious in view of the "target antigenic site" of claims 2-6 of the '301 patent. There is not extension of the rights granted under the '301 patent. In order to be covered by the claims of the present application, it is necessary to have a peptide immunogen that comprises the IgE-CH3 epitope of claims 3, 7 and 10 of the present application.

The claimed subject matter of the present application is novel over the subject matter of claims 2-6 the '301 patent. Moreover, the claimed subject matter of the present application, not being described, disclosed or taught by the '301 patent, cannot be rejected on the basis of non-statutory obviousness-type double patenting over claims 2-6 of the '301 patent.

The Examiner pointed to claims 2-6 of the '301 patent as reading on claims 3, 7, 10 of the present application. The Examiner stated that the target antigenic site of the '301 patent reads on the IgE-CH3 epitope of the present application. However, this is not the mandate. The mandate is to analyze claims 3, 7 and 10 of the present application and determine whether the subject matter of these claims is anticipated or obvious in view of claims 2-6 of the '301 patent, keeping in mind that the '301 patent is not to be treated as a prior reference.

In fact, a review of the analysis by the District Court of Delaware in the Pfizer v. Ranbaxy case cited above is instructive. The Court analyzed claims 12 and 14 of the earlier patent and determined that claim 12 is directed to a method of preparing certain lactone compounds and the opening of the lactone ring to form hydroxyl acids and pharmaceutically acceptable salts thereof. And, claim 14 is directed to the preparation of a single compound, atorvastatin lactone. The Court also construed the objected to claim 6 of the patent at issue as being directed to atorvastatin calcium.

Having construed claims 12 and 14 of the earlier patent and objected claim 6 of the patent at issue, the Court found that the process of claim 12 and the single compound of claim 14 are not contemplated by claim 6 and held that claim 6 is patentably distinct from claims 12 or 14 of the earlier patent.

Following this analysis, it is clear that a method of using promiscuous Th epitopes as defined by claims 2-6 of the '301 patent are not contemplated by claims 3, 7 and 10 which are directed to IgE-CH3 epitope linked to a promiscuous Th epitope, where claims 3, 7, and 10 define a patentably distinct invention.

Moreover, based on the restriction requirement that had issued in the parent application and other applications directed to peptides with specific sequences, it is clear that every combination of a specified B-cell epitope with a different specified Th epitopes is regarded as patentably distinct. Thus, the present rejection for double patenting is improper when the invention claimed as a whole has long been regarded by the Office as patentably distinct for purposes of a restriction requirement. The claims of the present application are a combination of specific B-cell epitopes of IgE-CH3 with specific promiscuous Th epitopes.

Since the claimed subject matter of the present application is different and distinct from the claims of the '301 patent, non-statutory obviousness-type double patenting in view of claims 2-6 of the '301 patent is improper and should be withdrawn."

It is the Examiner's position that she would like to direct Applicant's attention to Example 6 (Column 21, line 58 to Column 24, line 20) of U. S. Patent No. 6,713,301 (the '301 patent). Example 6 teaches a peptide immunogen for treatment of allergy comprising a T helper epitope sequence, the immunostimulatory invasin domain of SEQ ID NO:78 (which corresponds 100% over length and sequence to the immunostimulatory invasin domain of instant SEQ ID NO:13) and the target antigenic site of SEQ ID NO:92 (which corresponds 100% over length and sequence to the CH3 domain antigen peptide of instant SEQ ID NO:5).

There need not be a recital of "a target antigenic site" being a IgE-CH3 epitope or that the peptide immunogen for the treatment of allergy. Example 6 of the '301 patent teaches that SEQ ID NO:92 (which corresponds 100% over length and sequence to instant the CH3 domain antigen peptide of SEQ ID NO:5) is a "target antigenic site" and that the resulting immunogen can be used to treat allergy, contrary to Applicant's assertion that "there is no disclosure, description or suggestion of the IgE-CH3 B-cell epitopes of the present application in the '301 patent." Therefore, reading the specification, it would be obvious to one of ordinary skill in the art to make and use a peptide immunogen for treatment of allergy comprising a T helper epitope sequence, the immunostimulatory invasin domain of SEQ ID NO:78 (which corresponds 100% over length and sequence to the immunostimulatory invasin domain of instant SEQ ID NO:13) and the target antigenic site of SEQ ID NO:92 (which corresponds 100% over length and sequence to the CH3 domain antigen peptide of instant SEQ ID NO:5).

The Examiner is not asserting that that every combination of a specified B-cell epitope with a different specified Th epitopes is not to be regarded as patentably distinct. The Examiner is asserting that, in the instant case, the '301 patent has specifically taught the instantly claimed immunogen. Therefore, it would qualify as an unjustified or improper timewise extension of the "right to exclude" granted by a patent.

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 3, 2008

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

/

/Maher M. Haddad/

Primary Examiner, Art Unit 1644